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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,619	09/01/2009	David W. Old	17808 PCT US (AP)	1715

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EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1622	

NOTIFICATION DATE	DELIVERY MODE
12/15/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/599,619	OLD, DAVID W.
	Examiner	Art Unit
	MARK BERCH	1622

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7, 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. What does "interarylene" and "heterointerarylene" mean? Page 6, last 2 lines is noted. The examiner cannot determine how this term "interarylene" differs from "arylene". Is there any difference?
2. The term "one CH_2 may be substituted with S or O" is unclear. Ordinarily, this is a clear term. Substituted by means that H atoms are replaced with the substituent, so that CH_2 becomes C(O) or C(S). However, judging from the choices depicted on pages 9-11, what applicants intend is actually "replaced with", not "substituted with". The correct terminology must be used.
3. Claim 11 needs a carrier. It is clearly intended to be a liquid composition, but some soert of liquid carrier needs to be recited, since the compound is itself a solid.

4. The term "organic acid functional group" is unclear, because it is not clear how the term "functional" expands or limits the claim. If applicants intend just an organic acid group, they should so state.
5. A similar problem occurs with "tetrazolyl functional group". Is this just tetrazolyl itself? or is it any "functional" group which is substituted by a tetrazolyl, e.g. –CH(OH)-tetrazolyl?
6. The term "organic" in "organic acid functional group" is unclear. Is this intended to mean just carboxylic acids, or could it cover inorganic acids, so long as an organic piece was attached somewhere? For example, can Y be -CH_2-PO_3H_2? Could it be –S(O)(Nmethyl)OH?
7. But even if it is just carboxylic, the group is unclear. Presumably, it would be -X-COOH, but what is X?
8. The ether is unclear as to scope. It is -CH_2-O-Z, but what is Z?

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "comprising" in the first line of claim 1 is improper, as a compound cannot comprise (which is open-ended) a formula. One does not know what else is to be comprised. Suggested is replacing with "of".

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is impossible to tell what this claim is supposed to cover:

a. The phrase "a 4-(aryloxymethyl)azetidin-2-one" is unclear. What is at the 3-position? Can there be a second substituent at the 4-position?

b. The term "substituted at" is unclear. It is not clear whether the attachment must be direct, or whether it can be via a linker.

c. It is by no means clear what the scope of "alpha chain" is. There are substantial variations of what this can look like and the compound still can be considered a prostaglandin. It even includes chains that branch and make a second connection to the ring, as in Prostacyclin.

d. The last requirement is unclear. How is activity to be determined? What level of activity is needed to qualify as "active"?

Claims 7-9 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

The chiral bond at the lactam N in claims 2-7 is clearly in error. The N is not chiral.

However, in the event that applicants insist that the structure is drawn correctly, it is not enabled. Applicants have not shown how they can possibly have a chiral amide.

Claims 1-11 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention.

The term "metabolite" is indefinite. One does not know what compounds are and are not metabolites. Determining that a given compound is not a metabolite would be an endless task. One must check thousands of animals, and must check animals with impaired metabolisms, since sometimes a compound will be (or not be) generated in a person with a normal metabolism, but is (or is not) generated in a person with an abnormal metabolism. In addition, some metabolites are cleared so quickly by the body that they may be difficult or even impossible to detect.

In addition, the metabolites are not described. The specification contains no descriptions of what these actually look like.

In addition, the metabolites are not enabled. Some metabolites are active, but some (indeed, generally, most) are inactive, and the specification does not teach how the inactive metabolites are to be used.

The examiner notes that the claims encompass the esters of claim 1 of 12395813. However, the particular esters set forth in 12395813 for Y do not appear to be contemplated in 10599619. In 10599619, the most specific definition of the ester groups appears in the variable R2, which is set forth as alkyl, phenyl, or biphenyl (paragraph 0019) and hence (except as provided below) no ODP rejection is made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least

one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 12395813. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no line of patentable demarcation between the two.

Claim 3 of copending Application No. 12395813 corresponds to claim 8 in this case when n=0. Note that claim 3, unlike the other claims in the case including claim 1, does not have the special ester group seen in the choices for Y.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

The reference on the last page to a provisional application is improper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK BERCH whose telephone number is (571)272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew D. Kosar can be reached on (571)272-0913. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/
Primary Examiner
Art Unit 1622

12/9/2011